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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SEAN MCFERRAN

Appeal 2008-4655
Application 10/667,056
Technology Center 3700

Decided: December 18, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 13 and 15-17.¹ We have jurisdiction under 35 U.S.C. § 6(b).

¹ Claims 18-20 are also pending, but have been indicated as being allowable (App. Br. 3).

STATEMENT OF THE CASE

The claims are directed to a microcatheter. Claim 13 is representative of the claims on appeal, and reads as follows:

13. A single lumen microcatheter, comprising:
an elongate shaft having a distal end and a proximal end, the elongate shaft having an outer surface and an inner surface, the inner surface defining a lumen extending through the elongate shaft;
an elongate guidewire port positioned proximal to the distal end of the elongate shaft, the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and
a polymer sheath disposed over the elongate guidewire port, the polymer sheath having an inner surface and an outer surface, the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage.

The Examiner relies on the following references:

Alchas	US 5,030,210	Jul. 9, 1991
Person	US 5,807,349	Sep. 15, 1998

We affirm, but as our reasoning differs from that of the Examiner, we designate our affirmance as a new ground of rejection.

ISSUE

The Examiner concludes that rejects claims 13 and 15-17 are obvious over the combination of Alchas and Person.

Appellant contends that Alchas does not teach an elongate opening, and that there is no motivation to combine Alchas with Person to arrive at the catheter of claim 13.

Thus, the issue on Appeal is: Does the combination of Alchas and Person teach or suggest an elongate opening, and is there motivation to combine Alchas with Person to arrive at the catheter of claim 13?

FINDINGS OF FACT

FF1 According to the Specification, the invention is drawn to

a single lumen microcatheter having an elongate shaft that has a distal end and a proximal end. The elongate shaft can have an inner surface and an outer surface, and the inner surface can define a lumen that extends through the elongate shaft. A guidewire port can be positioned proximal of the distal end of the elongate shaft and can extend from the inner surface of the elongate shaft to the outer surface of the elongate shaft. A polymer sheath having an inner surface and an outer surface can be disposed over the guidewire port. The polymer sheath can include an angled slit that is in communication with the guidewire port. The angled slit can be configured to permit guidewire access through the guidewire port while remaining fluid tight when no guidewire is provided through the angled slit.

(Spec. 2.)

FF2 The Specification teaches further that the guidewire can have a defined width and defined length, but that it can also have “any other shape, such as a rectangular configuration or a round or oval configuration,” and that in certain embodiments, the guidewire port “can have a substantially round configuration.” (*Id.* at 8.)

FF3 Figures 6 and 7 are reproduced below:

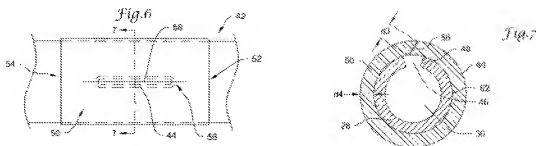


Figure 6 is a microcatheter according to the invention, wherein a polymer sheath including a control valve is disposed over the guidewire port (*Id.* at 3). Figure 7 is a cross-section of the microcatheter of Figure 6 taken along the line of 7-7 (*id.* at 4).

FF4 As shown in Figure 6, the polymer sheath 50 is “positioned proximate to and overlying the guidewire port 44.” (*Id.* at 8.) “The polymer sheath 50 includes a control valve 56 that can be configured to permit access through the polymer sheath 50 to the guidewire port 44 positioned beneath the polymer sheath 50.” (*Id.* at 9.)

FF5 The slit 58 (56 in Figure 7) can be formed at an angle other than perpendicular to the surface of the polymer sheath (as shown in Figure 7), such that it has a depth D3 that is greater than the thickness of the polymer sheath (*id.* at 10). “As a result, adjacent portions of the polymer sheath 50 (on either side of the slit 58) that contact each other when nothing is passed through the control valve will have increased surface area. In some embodiments, this can result in greater sealing and can provide greater resistance to inadvertently opening the slit 58 when not desired. Fluid

passed through the lumen can add pressure that assists in sealing the valve.” (*Id.* at 10-11.)

FF6 The Examiner rejects claims 13 and 15-17 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Alchas and Person (Ans. 3). As Appellant does not argue the claims separately, we focus our analysis on claim 13, and claims 15-17 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

FF7 The Examiner cites Alchas for disclosing “an elongate shaft (30), an elongate guidewire port (40), a polymer sheath disposed over the elongate guidewire port (34), wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage.” (*Id.*)

FF8 Figures 7 and 8, showing a catheter as taught by Alchas, are reproduced below.

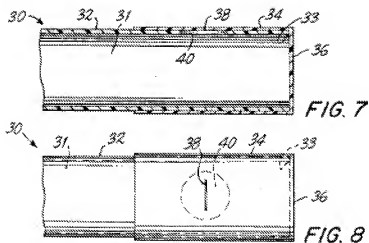


Figure 7 shows a partial longitudinal assembly of a catheter having a slit valve assembly, and Figure 8 is a top view of Figure 7 (Alchas, col. 4, l. 59).

FF9 Figure 7 shows a partial sectional view of catheter 32 with lumen 31, with a sheath 38 covering the catheter (*id.* at col. 5, ll. 54-58). An opening 40 is positioned in the wall of the catheter 42, and positioned in sheath 40 is a slit valve 38 over the top of the opening 40 (*id.* at ll. 59-62).

FF10 Alchas further teaches that “while the orientation of the slit valves shown in the end wall of the sleeve covering the distal end of the catheter is shown to be perpendicular to the longitudinal axis of the catheter, it should be understood that the slit may be oriented at various angles to the position shown.” (*id.* at col. 6, ll. 42-48.)

FF11 Thus, Alchas teaches or suggests all of the limitations of claim 13 except for specifically teaching that the opening in the wall of the catheter may be a shape other than circular, such as elongate, and forming the slit valve at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath.

FF12 Person is cited for teaching “an angled slit (82 and 84) extending radially through a polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath.” (Ans. at 4.)

FF13 The Examiner concludes “it would have been obvious to one of ordinary skill in the art [sic] at the time the invention was made to modify the sheath of Alchas with the angled slit described by Person for opening to increased pressure in the lumen to permit the infusion of fluids from the lumen of the catheter into the vessel in which the catheter is positioned (col. 5, lines 17-30).” (Ans. 4.)

FF14 The Examiner also finds that “Alchas in view of Person discloses the claimed invention except for the slit parallel along the longitudinal axis.”

(*Id.*)

FF15 The Examiner thus further concludes:

It would have been an obvious matter of design choice to position the slit parallel along the longitudinal axis, since applicant has not disclosed that the parallel slit over the angled slit solves any stated problem or is for any particular purpose and it appears that the invention would perform, equally well with the slightly angled slit as disclosed in the prior art of record. Or in the alternative one of ordinary skill in the art would have made a modification to make the slit parallel to the longitudinal axis [sic] because it would be an obvious modification and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (CCPA 1950), and that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

(*Id.*)

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and

creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 1739. “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 1740. Moreover, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). As noted by the Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” 127 S.Ct. at 1742.

ANALYSIS

Alchas teaches all of the limitations of claim 13, except for specifically teaching that the opening in the wall of the catheter may be a shape other than circular, and for forming the slit valve at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath (FF11). We conclude that it would have been obvious to use any shape opening in the wall that would accommodate Alchas’ slit valve and allow the catheter to function as disclosed, including an elongate opening, and that changing the shape of the opening would therefore be well within the level of ordinary skill.

As to the use of an angled slit, Person teaches that slit valves that are formed at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath are known in the art (FF12). Thus we conclude that it would have been obvious to one of ordinary skill in the art at

the time of the invention to angle the slit valve as taught by Person in the catheter of Alchas because the use of such angled slit valves were known, and appears to be a predictable variation.

In addition, it would have been obvious to orient the slit valve parallel to a longitudinal axis of the elongate shaft because Alchas teaches that the slit may be oriented at various angles (FF10).

Appellant argues that the Examiner found that Alchas teaches an elongate opening, but that “there is nothing in the specification of Alchas to suggest the opening 40 is elongate,” and that the figures depict the opening as perfectly circular (App. Br. 5).

We agree with Appellant that Alchas does not specifically disclose an elongate opening. However, as we note above, it would have well within the skill of the ordinary artisan to use any desired shaped opening, such as an elongate opening. Note moreover that claim 13 does not specify any particular dimensions for the elongate opening, thus it encompasses an opening which is just slightly wider than it is long, or vice versa.

Appellant argues further that there is no motivation to combine Alchas and Person (App. Br. 7). Appellant argues that Person is drawn to a double slit configuration, and thus “is not a neutral alternative configuration but a configuration that is inferior because it adds complexity without adding functionality.” (Reply Br. 3-4.)

As to orienting the slit longitudinally, Appellant argues that Person teaches away from such an orientation, by teaching that the slits would be in an area of reduced thickness (App. Br. 9). If one were to orient the slots of

Person longitudinally, Appellant asserts, “such a modification would reduce the size of the opening for the ingress and egress of fluids.” (*Id.* at 10.)

Appellant’s arguments are not convincing. Alchas is cited for teaching a slit in a polymer sheath over an opening in a catheter. Person is relied upon for providing evidence that angled slit valves were known in the art. Thus, it would have been well within the level of skill of the ordinary artisan to use an angled slit valve as the slit valve in Alchas as Person provides evidence that the use of angled slit valves were known to the ordinary artisan. As to orienting the slit longitudinally, Alchas specifically teaches that the slit may be oriented at various angles (FF10).

CONCLUSIONS OF LAW

We therefore conclude that the combination of Alchas and Person teach or suggest an elongate opening, and is that there motivation to combine Alchas with Person to arrive at the catheter of claim 13.

We thus affirm the rejection as to claim 13, and as claims 15-17 stand or fall with that claim, we affirm the rejection as to those claims as well. But as our reasoning differs from that of the Examiner, we designate our affirmance as a new ground of rejection.

TIME LIMITS

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this

paragraph shall not be considered final for judicial review.”

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED; 37 C.F.R. § 41.50(b)

Ssc:

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